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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,734	12/05/2003	Ring-Ling Chien	100/12330	1715
21569 7590 03/22/2007 CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234			EXAMINER VATHYAM, SUREKHA	
			ART UNIT	PAPER NUMBER
			1753	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/22/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.		Applicant(s)	
	10/728,734		CHIEN ET AL.	
	Examiner		Art Unit	
	Surekha Vathyam		1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/03, 05/05, 07/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for domestic priority under 35 U.S.C. 119(e) as a continuation-in-part of application 10/206,386, now abandoned, which is a continuation-in-part of application 10/013,847, now US Patent No. 6,695,009, which claims the benefit of provisional application 60/244,807. However, adequate support for the device geometry recited in claim 1 of the instant application (i.e., claim 1, lines 2 – 6) was not found in applications 10/013,847 or 60/244,807, and benefit of the earlier application dates for this aspect of the claimed invention is not

granted.**Specification**

2. The disclosure is objected to because of the following informalities:

In the Specification:

Page 1, paragraph [0001], line 2, after "2002," insert - - now abandoned,- -.

Page 1, paragraph [0001], line 2, after "2001," insert - - now US Patent No. 6,695,009,- -

Page 9, paragraph [0032], line 10, "690 (b (or" should be changed to - - 690 (b) or- -.

Page 14, paragraph [0047], line 8, "(e.g., 202a and 202b) connect with the main channel 204" should be changed to - - (e.g., 204a and 204b) connect with the main channel 202- -.

Page 17, paragraph [0057], line 6 and line 8, "304c" should be changed to - -302c- -.

Page 18, paragraph [0058], line 7, "pressure.." should be changed to - -pressure.- -.

Page 22, paragraph [0072], line 3, "to a alter" should be changed to - -to alter- -.

In the Claims:

Claim 1, line 15, "enhanced," should be changed to - -enhanced.- -.

Appropriate correction is required.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "210" has been used to designate both region (page 14, paragraph [0048], line 2) and fluid (page 14, paragraph [0048], line 5) and reference character "212" has been used to designate both region (page 14, paragraph [0048], line 3) and fluid (page 14, paragraph [0048], line 6).

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "400" (page 12, paragraph [0042], line 3); "408" and "410" (page 12, paragraph [0042], line 6); "300" (page 17, paragraph [0056], line 2); "700" (page 17, paragraph [0058], line 3); "416", "418" and "402a" (page 19, paragraph [0060], lines 10 – 11).

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "600", "692", "694" and "696" (Figures 6A – 6D).

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the

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application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 3 – 11, 16 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 2002/0008029 issued as US 6,818,113) in view of Parce et al. (US 5,869,004). NOTE: The column and line numbers of US 6,818,113 are indicated throughout this office action for Williams et al. for ease of identification of relevant sections as opposed to the published application US 2002/0008029.

Relevant to claim 1, Williams ('113) discloses a method comprising the provision of a device (Figure 1) comprising at least first, second, and third channels (26, 28, and 30) which intersect with and are fluidly coupled to a fourth channel (16) and a source of a sample material (38) in fluid communication with at least said first channel, wherein said first channel intersects said fourth channel at an opposite side of and at a channel region (32) which is located between the intersection of the second (34) and third (36) channels with the fourth channel; electrokinetically loading said sample material (column 8, lines 33 – 45) comprising at least a first species in a low conductivity buffer (column 11, lines 5 – 19) into the first channel and directing the sample material into the second and third channels via the fourth channel (column 8, lines 33 – 45) while concomitantly loading fluid of high conductivity buffer from opposite ends of the fourth

channel into the second and a third channels (column 8, line 33 – column 9, line 11 and column 11, lines 5 – 38) so that the low conductivity buffer of the sample material forms at least two fluid interfaces with the high conductivity buffer (Figure 1); and applying an electric field along a length of the fourth channel to concentrate at least said first species at at least one of said two fluid interfaces (column 10, lines 10 – 32).

Relevant to claim 3, Williams ('113) also discloses the concentration of species being increased by their method (column 10, lines 15 – 32).

Relevant to claims 4 and 11, Williams ('113) also discloses the sample material comprising a plurality of different materials (column 7, lines 23 – 39 and column 10, lines 15 – 32).

Relevant to claim 5, Williams ('113) also discloses at least first and second species being electrophoretically separated in the fourth column (column 10, lines 15 – 32 and column 11, lines 39 – 57).

Relevant to claim 9, Williams ('113) discloses a sample species comprising nucleic acids (column 7, lines 23 – 39).

Relevant to claim 10, Williams ('113) discloses a sample species comprising polypeptides (column 7, lines 23 – 39; broadly recited, proteins are polypeptides).

Relevant to claim 16, Williams ('113) discloses electrokinetically loading fluid of high conductivity buffer from opposite ends of the fourth channel into the second and third channels (column 8, lines 46 – 56).

Relevant to claim 18 Williams ('113) discloses said first and second species are oppositely charged and wherein said first species is concentrated at one of said two

fluidic interfaces and said second species is concentrated at the other one of said two fluidic interfaces during said applying step (column 10, lines 15 – 32).

Williams ('113) does not explicitly disclose the specific enhancement of detection of a material using the method (Claims 1, 3, 5). Furthermore Williams ('113) does not explicitly disclose: a second species being transported to a location other than a detection region (Claim 6), sample species that are specifically described as positively or negatively charged (Claims 7 and 8).

Parce ('004) explicitly discloses the enhanced detection of a material through a similar stacking method (column 15, lines 62-67). Relevant to claim 6, Parce ('004) also discloses a species from within the sample being transported to an area other than a detection region of the device (Figure 5E, Column 15, lines 54-59). Relevant to claims 7 and 8, Parce ('004) also discloses the use of either positively or negatively charged sample species (Column 15, lines 44-53).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Williams ('113) to use the stacking method for enhancement of detection of dilute materials, as taught by Parce ('004), because such stacking procedures provide convenient means of in situ sample concentration, allowing for analysis immediately following concentration as explained by Parce ('004) (column 13, lines 44 – 49).

Addressing claim 6, it would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Williams ('113) by transporting a second species within the sample material to a location other than a

detection region of the device, as taught by Parce ('004), because it could remove potentially interfering material from the subsequent steps of analysis.

Addressing claims 7 and 8, it would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Williams ('113) by specifically analyzing either positively or negatively charged sample species, as taught by Parce ('004), because the stacking method is effective in either case.

11. Claims 12 – 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 2002/0008029 issued as US 6,818,113) in view of Parce et al. (US 5,869,004) as applied to claim 1 above, and further in view of Williams et al. (US 2002/0079223 issued as US 6,685,813). NOTE: The column and line numbers of US 6,685,813 are indicated throughout this office action for Williams et al. for ease of identification of relevant sections as opposed to the published application US 2002/0079223.

Relevant to claims 12 – 15, Williams ('113) in view of Parce ('004) does not explicitly disclose the extent of concentration of sample species upon injection.

Williams ('813) discloses application of an electric field of sufficient magnitude and duration for over 100-fold concentration relevant to claims 12 – 15 (column 9, lines 18 – 38).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Williams ('113) in view of Parce ('004) by

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applying an electric field of sufficient magnitude and duration to concentrate a species within the sample at least 100-fold, as taught by Williams ('813), because it would facilitate detection of dilute sample components.

Relevant to claim 17, Williams ('113) in view of Parce ('004) does not explicitly disclose the hydrodynamic loading of the high conductivity buffer.

Williams ('813) discloses the hydrodynamic loading of material (Figures 3A - 3D; column 8, line 62 – column 9, line 17).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Williams ('113) in view of Parce ('004) by loading the high conductivity buffer hydrodynamically as taught by Williams ('813), because it would eliminate concern of electrophoretic bias and resulting non-representative sampling of the analyte(s).

12. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 6,818,113) in view of Parce et al. (US 5,869,004) as applied to claim 1 above, and further in view of Kopf-Sill (US 6,001,231).

Relevant to claim 2, Williams ('113) in view of Parce ('004) does not explicitly disclose the use of the method to analyze an antibody/antigen mixture.

Kopf-Sill ('231) discloses the electrophoretic analysis of an antibody/antigen mixture in a microfluidic system (Column 14, line 28 - Column 15, line 3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Williams ('113) in view of Parce ('004) by using the method to analyze antibody/antigen mixtures, as taught by Kopf-Sill ('231), because it would allow enhanced detection of dilute antibody/antigen mixtures. Kopf-Sill ('231) also suggests broad applicability of known methods within the invention (Column 8, lines 32-55), and refers to control of concentrating procedures in the specification (Column 9, lines 25-29).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Surekha Vathyam whose telephone number is 571-272-2682. The examiner can normally be reached on 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SV
March 16, 2007


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